

### REMARKS

The Applicants appreciate the Examiner's thorough examination of the subject application. Applicants request reconsideration of the subject application based on the following remarks.

94 and 108-120 are currently pending in the application. Claim 94 has been amended and new claims 108-120 have been introduced. Support for the new claims and the amendments to claim 94 can be found throughout the application as filed. No new matter has been introduced by the instant amendments.

More particularly, support for the claims as amended can be found in the specification as follows:

- Support for claim 108 appears in page 39 line 17 to page 42 line 4 from the bottom, and Examples 1, 2, 3, 5, 6, 8, 9, 10, 11, 12, 13 and 14.
- Support for claim 109 appears in page 25 last paragraph, and Examples 1, 2 and 5.
- Support for claims 110 and 111 appears in page 46 line 18 to page 47 line 6 from the bottom, and Example 8.
- Support for claim 112 appears in page 76 line 13 to page 78 line 3 and Examples 4, 7, 15, 16, 23.
- Support for claim 113 appears in page 44 lines 5-7, Examples 7, 15 and 16.
- Support for claim 114 appears in Example 23.
- Support for claim 115 appears in page 74 line 12 to page 75 line 2. Preferable dose range of 5.625g – 36g a day for 60kg human means “94mg/kg/day to 600mg/kg/day”.
- Support for claim 116 appears in page 75 line 15 to page 76 line 12. Preferable dose range of 1.5g – 6g a day for 60kg human means “25mg/kg/day to 100mg/kg/day”.
- Support for claim 117 appears in page 103 line 10 to page 104 line 6.
- Support for claim 118 appears in page 103 line 10 to page 104. The dose “1/10 to 1/100,000 of 14.5µg/kg/day to 1450µg/kg/day” means “145pg/kg/day to 145µg/kg/day”.

- Support for claim 119 appears in page 91 line 22 to page 93 line 11. The dose range “1.2mg – 12mg/day for body weight 60kg” means “20 $\mu$ g/kg/day to 200 $\mu$ g/kg/day”.
- Support for claim 120 appears in page 93 line 3 to 11, and Examples 15 and 23. The upper limit of daily dose or dosage of ginsenoside Rb<sub>1</sub> for the therapy, prevention or treatment of brain and nervous diseases and the other diseases is 0.1g (100mg) per patient weighing 60 kg. The lower limit of daily dose or dosage of ginsenoside Rb<sub>1</sub> for the therapy, prevention or treatment of brain and nervous diseases is 0.01mg per patient weighing 60kg and that of ginsenoside Rb<sub>1</sub> for the therapy, prevention or treatment of diseases other than the brain and nervous diseases is 0.01mg or 1/10 to 1/100,000 of 0.01mg per patient weighing 60kg. Accordingly, the dose ranges of ginsenoside Rb<sub>1</sub> for the therapy, prevention or treatment of brain and nervous diseases and the other diseases are 0.167 $\mu$ g/kg/day - 1.67mg/kg/day and 1.67pg/kg/day - 1.67mg/kg/day, respectively.

The specification has been amended to incorporate a claim of priority to the copending international application, PCT/JP00/04102 filed June 22, 2000, which international application claims priority from Japanese application JP 11-243378, filed August 30, 1999. Thus, the priority claim has been perfected.

The specification was objected to as failing to provide a Brief Description of the Drawings and the application allegedly did not contain an abstract of the disclosure.

The specification as filed provides a Brief Description of the Drawings. See pages 30-37 of the specification.

The application as filed included an Abstract of the Invention. A copy of the original abstract is included as Appendix A.

The specification and Abstract are fully compliant with Rules 1.72(b) and 1.75. Thus the objections to the specification should be withdrawn.

The Form PTO-1449 filed with the Information Disclosure Statement on February 28, 2002 was objected to for failing to list the authors and the titles of the references. Corrected Form PTO-1449, which provide the author and title information for each document, are attached as Appendix B.

Claims 94-96 were rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Arikhbaieff (French Patent Number 2,648,046).

The rejection is traversed.

For the Examiner's convenience, an English Language translation of the French language Arikhbaieff patent is enclosed as Appendix C.

The office action asserts that Arikhbaieff recites a method for enhancing immune function via the administration of a beverage which included red ginseng comprising saponins.

The office action further asserts that "the term 'disease' was given its broadest interpretation, and it is deemed that immune dysfunction is a 'disease'". Moreover, the office action asserts that the Arikhbaieff patent teaches administration of a composition comprising ginseng to a patient would have inherently performed this mechanism (enhancing immune function) because it is the same composition *given to the same group of patients*.

The claims as amended are drawn to methods of treating a mammal suffering from or susceptible to diseases causing apoptosis or apoptosis-like death of cells wherein the treatment of immune deficiency diseases or disorders are expressly excluded. Support for claim 94 as amended is provided by the specification.

The present invention provides the method of inhibiting apoptosis or apoptosis-like death

of cells by administering ginseng, or ginseng components. Moreover the present invention demonstrates the mechanism of apoptosis inhibition; to be more specific, administration of ginseng or ginseng components is shown to stimulate the expression of Bcl-xL protein that is known as an apoptosis suppressor (See Example 3, 4, 13, 14 and 15 in the present specification). The present invention also demonstrates that administration of ginseng or ginseng components prevents neuron death or nervous tissue lesion in a mammal suffering from cerebral infarction or spinal cord injury (See Example 1, 2, 5, 8, 9, 10 and 11).

In contrast, the Arikhbaieff patent recites the methods of treating immune deficiencies in patients where the method of treatment comprises the administration of red ginseng powder to a patient to ***improve antibody production*** as assessed by a hemagglutination test (See the CONCLUSION of Arikhbaieff).

One skilled in the art would not reasonably infer that a therapeutic agent capable of increasing antibody production would be capable of inhibiting cell apoptosis.

Thus, for at least the reasons discussed herein, claim 94 as amended is patentably distinct from the disclosure of the Arikhbaieff patent.

Reconsideration and allowance of claims 94 and 108-120 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance.. Applicant respectfully requests early consideration and allowance of the subject application.


If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned agent would appreciate the opportunity to do so.

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Respectfully submitted,



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